Merit Medical Systems, Inc.
ReSolve® Biliary Drainage Catheter
PREMARKET NOTIFICATION [510(k)]
CONFIDENTIAL
510(k) Summary

Submitter

Merit Medical Systems, Inc.
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Establishment Registration Number

1721504

Contact Person(s)

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NOV 1 4 2007

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Date Prepared

December 15, 2006

Name of Medical Device

Classification Name:	Catheter, Biliary, Diagnostic (21 CFR 876.5010)
Common/Usual Name:	Biliary Drainage Catheter
Trade/Proprietary Name:	ReSolve® Biliary Drainage Catheter

Device Classification

Panel:	Gastroenterology – Urology Devices
Device Class:	Class II
Product Code:	FGE
Regulation Number:	21 CFR 876.5010

Predicate Device Identification

Device Brand Name	UreSil Hydrophilic-coated Chole-Cath® Biliary Drainage Catheter
Classification Name	Catheter, Biliary, Diagnostic (21 CFR 876.5010)
Device Class	Class II
Classification Panel Number	876
Product Code	FGE
Clearance Status	K981344
Manufacturer	Uresil L.P.
Registration Number	1450395

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Device Description

The Resolve® Biliary Drainage Catheter consists of single lumen tubing with two suture holes and 17 to 18 drainage holes in the distal curve region. It is made from a biocompatible thermo-plastic. A hydrophilic coating reduces entry site/catheter friction during placement. The components of the catheter allow initial placement using an over-the-wire technique. These include a metal stiffener, flexible plastic stiffener, straightener and repositioning tool. The pigtail straightener is provided to assist in feeding the guide wire through the catheter. Once the catheter position is established in the area to be drained, the pigtail is formed by retracting a suture which is looped from the hub, to the catheter tip and back to the hub.

The hub incorporates a suture locking mechanism to retain the distal pigtail shape. It may be unlocked using the repositioning tool to allow repositioning or replacement of the catheter. A single radiopaque marker band is located proximal to the most proximal drainage hole to assist in accurate placement of the drainage holes in the biliary duct.

Intended Use

The Resolve® Biliary Drainage Catheter with locking pigtail and hydrophilic coating is used for drainage of bile within the biliary system.

Summary of Characteristics in Relation to the Predicate Device

Does the new device have the same indication statement as the predicate device?

Yes.
Although there are minor differences, the intended use is the same.

Does the new device have the same technological characteristics, e.g., design, materials, etc. as the predicate device?

Yes.
The Resolve® Biliary Drainage Catheter employs a similar method of operation and design as compared to the predicate device. Both the new and predicate devices consist of a hub, shaft with pigtail tip, drainage holes on the distal end and a pigtail locking mechanism. Both the new and predicate devices are comprised of similar materials and are the same sizes.

Are the descriptive characteristics precise enough to ensure equivalence to the predicate device?

No.
Bench testing was conducted on the Resolve® Biliary Drainage Catheter in order to establish substantial equivalence.

Are performance data available to assess effects of the new device as compared to the predicate device?

Yes.
Performance testing was conducted according to international standards as well as Merit's in-house protocols. Where performance could affect the safety or effectiveness of the Resolve® Biliary Drainage Catheter, comparison tests with the predicate device was conducted.

Does performance data demonstrate equivalence?

Yes.
Performance data demonstrates that the Resolve® Biliary Drainage Catheter is substantially equivalent to the predicate device.

Conclusion: "Substantial Equivalence" Determination

Based on CDRH's substantial equivalence decision tree, the Resolve® Biliary Drainage Catheter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2007

Ms. Amy E. McKinney
Regulatory Affairs Consultant
Merit Medical Systems, Inc.
1111 South Velasco
ANGLETON TX 77515

Re: K063733
Trade/Device Name: ReSolve Biliary Drainage Catheter
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: October 31, 2007
Received: November 1, 2007

Dear Ms. McKinney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATION(S) FOR USE STATEMENT *

510(k) Number (if known):

Device Name: ReSolve® Biliary Drainage Catheter

Indications for Use:

The Resolve® Biliary Drainage Catheter with locking pigtail and hydrophilic coating is used for drainage of bile within the biliary system.

Prescription Use ___X___ (Part 21 CFR 901 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart O)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063733